DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Spine
Mr. Alan Traettino
Senior Director, Regulatory and Clinical Affairs
2 Pearl Court
Allendale, New Jersey 07401

November 13, 2014

Re: K142066
Trade/Device Name: Aero™-LL Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: October 20, 2014
Received: October 21, 2014

Dear Mr. Traettino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142066

Device Name
Aero™-LL Lumbar Cage System

Indications for Use *(Describe)*
The Stryker Spine Aero™-LL is an intervertebral body fusion device indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy.

The Aero™-LL Lumbar Cage System is to be implanted via a lateral approach.

The Aero™-LL Lumbar Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems). In addition, the device may be used with or without the included fixation anchors.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

| 510(k) Summary: Aero™-LL Lumbar Cage System | |
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| Submitter: | Stryker Spine<br>2 Pearl Court<br>Allendale, New Jersey 07401 |
| Contact Person | Alan Traettino<br>Senior Director, Regulatory and Clinical Affairs<br><br>Phone: 201-760-8109<br>Fax: 201-962-4109<br>Email: alan.traettino@stryker.com |
| Date Prepared | October 20, 2014 |
| Trade Name | Aero™-LL Lumbar Cage System |
| Proposed Class | Class II |
| Classification Name and Number | Intervertebral body fusion device, 21 CFR 888.3080 |
| Product Code | OVD, MAX |
| Predicate Devices | The Aero™-LL Lumbar Cage System was shown to be substantially equivalent to the devices listed below:<br>Primary Predicate Device:<br>Stryker Spine *AVS PL* (K082014)<br>Additional Predicate Devices:<br>Stryker Spine *Aero™-AL Lumbar Cage System* (K133328)<br>Stryker Spine *AVS Anchor-L* (K120869)<br>LDR Spine *Avenue L* (K113285)<br>Depuy Synthes *SYNFIX Lateral Spacer* (K131276) |
| Device Description | The Aero™-LL Cage is a hollow, bullet-shaped PEEK Optima cage surrounded by a titanium alloy (Ti-6Al-4V) jacket. The PEEK Optima cage portion consists of two closed pockets for graft containment and has serrations on the superior and inferior surfaces of the cage. The implant is designed to be used either with or without the internal supplemental fixation provided (Aero™-LL Fixation Anchors) in addition to supplemental fixation systems cleared for use in the lumbosacral spine. The Aero™-LL Fixation Anchors are constructed from titanium alloy (Ti 6Al-4V) and feature rails that mate with dovetail channels located within the Aero™-LL PEEK cage. Once fully seated into the channels, the anchors are designed to lock into the titanium jacket. |
| Intended Use and Indications for Use | The Stryker Spine Aero™-LL is an intervertebral body fusion device indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.<br><br>DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should |

| 510(k) Summary: Aero™-LL Lumbar Cage System | |
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| | be skeletally mature and have six months of nonoperative therapy.<br><br>The Aero™-LL Lumbar Cage System is to be implanted via a lateral approach.<br><br>The Aero™-LL Lumbar Cage System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems). In addition, the device may be used with or without the included fixation anchors. |
| Summary of the Technological Characteristics | The subject Aero™-LL Lumbar Cage System and the predicates share similar design features:<br>• Graft windows for packing autogenous bone<br>• Serrations on the superior and inferior surfaces<br>• Comparable heights, widths, depths, and lordotic angles |
| Summary of Non-Clinical Testing | Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the Aero™-LL Lateral Lumbar Cage System and demonstrated substantially equivalent performance to the identified predicate device systems.<br>The following mechanical tests were performed:<br>• Static Compression (per ASTM F2077)<br>• Dynamic Compression (per ASTM F2077)<br>• Static Compression Shear (per ASTM F2077)<br>• Dynamic Compression Shear (per ASTM F2077)<br>• Static Torsion (per ASTM F2077)<br>• Dynamic Torsion (per ASTM F2077)<br>• Expulsion (per ASTM F04-25-02-02 Draft)<br>• Subsidence (per ASTM F2267)<br>• Wear Debris Assessment<br>• Dynamic Cadaver Testing involving the implantation of the Aero™-LL device into multiple functional spinal units and subsequent evaluation of fatigue performance under multiple loading modes. |
| Conclusion | Based upon a comparison of intended use, technological characteristics, and device performance in the non-clinical testing listed above, the Aero™-LL Lateral Lumbar Cage System has demonstrated substantial equivalence to the identified predicate device systems. |